

**Indiana State Department of Health
Serious Adverse Event Reporting Rule
410 IAC 15-1.4-2.2**

**Economic Impact on Small Business Statement
Pursuant to IC 4-22-2.1
LSA # 05-193**

January 10, 2006

Description of Rule:

The Indiana State Department of Health (ISDH) has responsibility for the licensure and regulation of hospitals pursuant to IC 16-21. In January 2005, Governor Daniels issued Executive Order 05-10 requiring the ISDH to develop and implement a medical errors reporting system (MERS). In response to the Executive Order, the Hospital Council recommended and the ISDH Executive Board preliminarily adopted rules requiring the reporting of medical errors resulting in death or serious disability.

The proposed rule is based on the National Quality Forum's twenty-seven (27) serious reportable events or 'never' events as they are frequently called. The proposed rule requires hospitals to have a serious adverse event reporting system in place by January 1, 2006 and requires reports of serious adverse events to be submitted to the ISDH not later than fifteen (15) days after the serious adverse event occurs. Data submission will occur online in real time utilizing the existing ISDH electronic portal. Hospitals must review the serious adverse events through their quality assessment and improvement program. The ISDH is required to analyze and publish the data no less than annually.

Fiscal Impact

Indiana Code 4-22-2-28(c) requires an agency to submit to the Office of Management and Budget any proposed rule with an estimated economic impact of greater than five hundred thousand dollars (\$500,000) on all persons regulated by the rule. After the preliminary adoption of such a rule, the Office of Management and Budget must prepare a fiscal impact statement concerning the effect that compliance with the proposed rule will have on the state and all persons regulated by the proposed rule.

The department has reviewed the proposed rule to determine whether the total economic impact of the rule on regulated persons will exceed \$500,000. The department has determined, based on the information available at the time of the rule promulgation, that the proposed rule does not have an estimated economic impact of greater than five hundred thousand dollars (\$500,000) on the persons regulated by the rule. The ISDH therefore did not submit the proposed rule to the Office of Management and Budget prior to the rule being adopted.

Economic Impact on Small Businesses

1. Estimate of the number of small businesses, classified by industry sector, that will be subject to the proposed rule.

IC 4-22-2.1-4 defines a small business as any person, firm, corporation, limited liability company, partnership, or association that:

- (1) is actively engaged in business in Indiana and maintains its principal place of business in Indiana;
- (2) is independently owned and operated;
- (3) employs one hundred (100) or fewer full-time employees; and
- (4) has gross annual receipts of five million dollars (\$5,000,000) or less.

The ISDH licenses 140 hospitals. The North American Industry Classification System classifies these institutions as General Medical and Surgical Hospitals (NAICS 622110). The ISDH reviewed data reported by the licensed hospitals. After review of the most recent data submitted by Indiana hospitals, the ISDH has determined that no Indiana hospitals regulated by the proposed rule meet the definition of a small business. All Indiana hospitals reported gross annual receipts in excess of five million dollars. Nineteen hospitals reported fewer than one hundred full-time employees but most, if not all of these hospitals, are not independently owned and operated. These are primarily long term care hospitals classified as hospitals within hospitals.

Conclusion

Because no Indiana hospitals licensed under this rule are a small business, there is no economic impact of the proposed rule on small businesses.